ORDER OF MALTA
FEDERAL ASSOCIATION, USA

January 18, 2005

Lester Crawford, M.D., Acting Commissioner
US Food and Drug Administration
1471 Parklawn Building
5600 Fishers Lane
Rockville, MD 20857

Re: Comments on FDA Proposed Rule on Use of Ozone-Depleting Substances; Removal of Essential Use Designations (FDA Docket No. 2003P-0029)

Dear Dr. Crawford:

I am the Chief Medical Advisor to fifteen indigent-care clinics operating in the District of Columbia and twelve states under the auspices of the Sovereign Military Order of Malta, a Roman Catholic Hospitaller order. Each of our indigent-care clinics provide acute and chronic medical services to low-income working families and others in need that have no other ready access to care. A significant portion of our case load involves patients suffering from serious respiratory diseases including asthma and COPD.

I am submitting comments to the FDA Docket because I am concerned that the dwindling supply of CFCs could threaten a smooth and appropriate transition in this country from CFC albuterol metered-dose inhalers (MDIs) to CFC-free medicines. It would be extremely unfortunate if regulatory delay in establishing policy to change, as required, to CFC-free medicines resulted in a crisis for physicians and patients who had not been prepared for this eventuality. I am convinced that FDA action to ensure transition to CFC-free albuterol MDIs by December 31, 2005 is in the best interests of the patients we treat. I urge FDA to move as rapidly as possible to achieve this deadline.

There are currently three CFC-free albuterol MDIs available to patients. The suppliers have indicated they can provide a sufficient supply of albuterol MDIs to meet patients' needs. In addition, I believe phasing-out CFC albuterol MDIs and transitioning the market to CFC-free medicines will benefit respiratory patients since I view the transition as providing an excellent opportunity for physicians and other healthcare providers to review and improve patients' treatment plans. Many patients currently rely on inappropriate therapies such as the excessive use of albuterol-containing rescue

2003P-0029 C38

1730 M STREET, NW SUITE 403 WASHINGTON, DC 20036
202-331-2494 FAX 202-331-1149 INFO@SMOM.ORG

medicines. Revising treatment plans to emphasize the use of maintenance medicines will help patients better manage their asthma and COPD.

For these reasons, it is imperative that FDA move rapidly to phase-out CFC albuterol MDIs by December 31, 2005. Thank you for your serious consideration of this important matter.

Sincerely,

Constance Battle, M.D.

Constance U. Battle, M.D.
Chair, Domestic Clinic Committee, SMOM, Federal Association - USA
Clinical Professor of Pediatrics, School of Medicine
Adjunct Professor of Prevention and Community Health, School of Public Health
The Georgetown Washington University